

FIG. 1A

	-42 [†] to -30 [†]	-20 [†] to -12 [†]	1	7	10	17	24	31	38	45										
Day of Study	to -30	to -12		1	7	10	17	24	31	38	45									
Week of Study	-30	-12			1	2	3	4	5	6	7									
Month of Study																				
Surgery	X																			
Informed Consent		X																		
Randomize		X																		
Cyclophosphamide					X															
BCG						XA	XA	XB	XB	XC	XC				XC					
Vaccine			X			X	X	X	X	X	X				X					
History/Physical Exam	X		X			X	X	X	X	X	X	Xe	Xe	Xe	Xe	Xe	Xe	Xe	Xe	Xe
Vital Signs	X	X	X			X	X	X	X	X	X	Xe	Xe	Xe	Xe	Xe	Xe	Xe	Xe	Xe
Performance Status	X	X	X			X	X	X	X	X	X	Xe	Xe	Xe	Xe	Xe	Xe	Xe	Xe	Xe
Routine Labs**	X	X	X			X	X	X	X	X	X	Xe	Xe	Xe	Xe	Xe	Xe	Xe	Xe	Xe
Pregnancy (HCG)	X	X																		
Hepatitis/HIV	X	X																		
Chest X-Ray									Xe			Xe			Xe		Xe			
CT or MRI	X	X										Xe			Xe					Xe

A-----A

FIG. 1B

A ————— A

† This can be extended up to -56 days only if an additional procedure is needed to establish that the patient is melanoma-free prior to randomization

* History/Physical Exam, Vital Signs, Performance Status, Routine Labs, Chest X-Ray q2 months in year 2, q3 months in year 3, then q6 months through year 5; CT or MRI at 18, 24, and 36 months (chest x-ray omitted if CT/MRI scheduled)

XA 0.1 mL of a 1:10 dilution of Tice BCG (Tice-A) mixed with vaccine

XB 0.1 mL of a 1:100 dilution of Tice BCG (Tice-B) mixed with vaccine

XC 0.1 mL of a 1:1000 dilution of Tice BCG (Tice-C) mixed with vaccine

‡ This can be extended up to -34 days if an additional procedure is needed to establish that the patient is melanoma-free prior to randomization

‡‡ Routine Labs: hematology (CBC with differential, platelet count), BUN or creatinine, LDH, SGOT, alkaline phosphatase, electrolytes

<e End of Treatment Month